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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,539	10/16/2003	Kevin T. Foley	5074A-000067	7710

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EXAMINER	
KISH, JAMES M	

ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/687,539	FOLEY ET AL.	
	Examiner	**Art Unit**	
	JAMES KISH	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 23 September 2009.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-15,17,18,20-48,50,52-73 and 75-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-15,17,18,20-48,50,52-73 and 75-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 23, 2009 has been entered.

Response to Arguments

Applicant's arguments filed July 22, 2009 have been fully considered but they are not persuasive.

The Applicant argues that none of the prior art references teaches tracking multiple tracking devices at the same time. *See* page 29 of the Remarks. These remarks were addressed in the Advisory Action dated September 11, 2009. See as follows:

> *Regarding claims 1, 22, 33, 53 and 67, the Examiner cites Foley as teaching, "a processor… for modifying the image data set according to the identified relative position of each of the reference points during the procedure. The processor can then… generate an image data set representing the position of the body elements during the procedure for*

display on [a] monitor. A surgical instrument… may be included in the system, which is positioned relative to a body part and similarly tracked (column 6, lines 21-37)." It should be highlighted that this quote states, "representing the position of the body elements during the procedure," wherein this is plural. Therefore, more than one element is being tracked. As shown in Figure 1, there are several elements being tracked, each of which are represented on the monitor 106. Therefore, Foley teaches a processor that is configured to track multiple elements. The claims state, "a substantially patient imageless manner." The term "substantially" is indefinite and it is unclear how substantial the image should be considered in such a system. Nonetheless, Ellis teaches the paradigm of imageless surgery and provides a comparison to image guided surgery, which would lead one of skill in the art to consider the imageless manner. The Applicant argues that Foley fails to teach a tracking system that may track more than one element at a time. The Examiner respectfully disagrees. When the tracking sensors of Foley are activated, they will track any and all trackable elements within its field of view. "The general operation of a surgical navigating system is well known in the art and need not further be described here (column 6, lines 38-40)." It is obvious to one of skill in the art that more than one tracking element would be tracked simultaneously in order to perform a delicate surgery where more than one invasive device is being used.

These remarks still apply the current claims and, for at least these reasons, the rejection of the claims as previously presented still stand.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9, 11-15, 17-18, 22-30, 33-44, 47-48, 50, 52-73, 77-80, 82, 85, 88, and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley et al. (US Patent No. 6,226,548) in view of Ellis (US Patent App. No. 2003/0011624).

Claims 1-3 and 78:

In an alternative interpretation of Claim 1, Foley describes a system that uses at least six separate pedicle screws 250 as shown in Figures 12 and 13. One of these is considered the first member. This first member is illustrated in Figure 7A as having a fastening portion 250 and an engageable portion (represented by the slots removed from the head of the screws). Second member is illustrated in Figure 8 as item 360. The third member is illustrated in Figure 8 and is represented by the unlabeled fasteners that are protruding upward from the head of the first member 250 and simultaneously through second member 360. A localization element is found in Figure 7. Detection unit 110 of Figure 1 comprises an optical tracking unit along with processor 114. The localization element provides navigational information for all three members.

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and tracking devices are attached to a patient in order to guide the intervention free of imaging. See paragraphs 3-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

Regarding claim 78, see Figure 7A of Foley.

Claims 1, 4-9, 11-18 and 80:

Foley describes a system comprising a detection unit 110 of Figure 1 and subsequently, tracking elements for the system comprise an optical tracking system. Localization element is found in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first, second, and third members. Each member is illustrated in Figure 7A as having a fastening portion 250 and an engageable portion (represented by the slots removed from the head of the screws). The localization element provides navigational information for all three members and is illustrated in Figures 7 and 8. A fourth member 360 in Figure 9 engages first, second and third (not shown in Figure 9, *see* Figure 8) members.

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and tracking devices are attached to a patient in order to guide the intervention free of imaging. See paragraphs 3-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

With respect to **Claim 8**, *see* column 9, lines 51-58.

With respect to **Claim 9**, Figure 8 illustrates that when localization occurs, both first and second member will include a localization element extending therefrom.

With respect to **Claim 14**, *see* column 9, lines 38-43.

With respect to **Claim 15-16**, *see* column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional. Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

With respect to **Claim 80**, column 10, lines 29-33 of Foley discuss that an alternative to imaging operator could provide a clamp or screw and superstructure rigidly fixed to each vertebra involved in the surgical or medical procedure to register the position of each vertebra. It is obvious that the display would be able to differentiate the separate superstructures in order to create an understandable view to the operator.

Claims 22-29:

Foley describes a system comprising a detection unit 110 of Figure 1, which comprises at least three separate detection device. The multiple detection devices create a sensor array and in turn represent the detection unit. The tracking elements for the system comprise an optical tracking system. Localization element is found in Figure 7. Also included in the system is a

processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first and second members and can be placed in the vertebrae prior to scanning (*see* column 9, lines 46-47). The localization element provides navigational information for both members and is illustrated in Figures 7 and 8. Figure 12 demonstrates the members after implantation. Figure 13 demonstrates the final position of the members after manipulation via probe 280, as shown in Figure 8.

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and tracking devices are attached to a patient in order to guide the intervention free of imaging. See paragraphs 3-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

With respect to **Claim 28-29**, *see* column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional. Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

Claims 33-44, 47-48, 50 and 52:

Foley describes a system comprising a detection unit 110 of Figure 1 and subsequently, tracking elements for the system comprise an optical tracking system. The tracking element is shown in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first, second, and fourth members. The tracking element provides navigational information for all three members and is illustrated in Figures 7 and 8. Figures 12 and 13 illustrate the determination of a selected alignment of the first, second and fourth members in relation to each other. A third member 360 in Figure 9 engages first, second and fourth (not shown in Figure 9, *see* Figure 8) members. During insertion, an optically tracked rod inserter can be utilized to guide the third member 360 through the slots of the first, second and fourth members (*see* column 10, lines 63-67). The rod geometry could also be visible and shown in real-time on monitor 106 as the operator is placing it in the other members (*see* column 11, lines 10-13). Also, the operator can use the computer to determine the required bending angles, or optimal position, of the rod (*see* column 11, lines 3-5).

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and tracking devices are attached to a patient in order to guide the intervention free of

imaging. See paragraphs 3-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

With respect to **Claim 38**, the third member would be required to be flexible to allow for the computer to determine a required bend.

With respect to **Claims 43-44**, *see* column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional. Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

Claims 53-66 and 79:

Foley describes a system comprising a detection unit 110 of Figure 1 and subsequently, tracking elements for the system comprise an optical tracking system. The tracking element is shown in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first, second, and fourth members. The tracking element provides navigational information for all three members and is illustrated in Figures 7 and 8. Figures 12 and 13 illustrate the determination of a final orientation of the first, second and fourth members in relation to each other,

excluding a third connecting member. The third member 360 in Figure 9 engages first, second and fourth (not shown in Figure 9) members. Figure 8 illustrates a final orientation including the third member. During insertion, an optically tracked rod inserter can be utilized to guide the third member 360 through the slots of the first, second and fourth members (*see* column 10, lines 63-67). The rod geometry could also be visible and shown in real-time on monitor 106 as the operator is placing it in the other members (*see* column 11, lines 10-13). Also, the operator can use the computer to determine the required bending angles, or optimal position, of the rod (*see* column 11, lines 3-5). Since bending is required, the third member would need to be flexible to allow for the computer to determine a required bend.

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and tracking devices are attached to a patient in order to guide the intervention free of imaging. See paragraphs 3-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

With respect to **Claim 60**, *see* column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional. Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

With respect to **Claim 79**, see Figure 7A of Foley.

Claims 67-72:

Foley describes a system comprising a detection unit 110 of Figure 1, which comprises at least three separate detection device. The tracking elements for the unit comprise an optical tracking system. The tracking element is found in Figure 7. Also included in the system is a processor 114. At least six separate pedicle screws 250 as shown in Figures 12 and 13. These are the first and second members and can be placed in the vertebrae prior to scanning (*see* column 9, lines 46-47). The localization element provides navigational information for both members and is illustrated in Figures 7 and 8. Figure 12 demonstrates the members after implantation. Figure 13 demonstrates the final position of the members after manipulation via probe 280, as shown in Figure 8.

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and

tracking devices are attached to a patient in order to guide the intervention free of imaging. See paragraphs 3-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

With respect to **Claim 71-72**, *see* column 4, lines 16-24. The realignment of the vertebrae will also realign the pedicle screws placed in the vertebrae. Also, at column 3, lines 33-36 it is stated that the images are three-dimensional. Therefore, the processor would align the vertebrae, and subsequently the screws, in three-dimensions.

Claims 67 and 77:

In alternative interpretation of Claim 67, Foley describes a system comprising a detection unit 110 of Figure 1, which comprises at least three separate detection device. The tracking elements for the unit comprise an optical tracking system. The tracking element is found in Figure 7. Also included in the system is a processor 114. A first member is illustrated in Figures 2 and 2A-C. The first member comprises four members, or LEDs 122. These LEDs represent the first member's first, third and fourth members. At least six separate pedicle screws 250 are shown in Figures 12 and 13. Any one of these can be

considered the second member and can be placed in the vertebrae prior to scanning (*see* column 9, lines 46-47). The tracking element provides navigational information for the second member and is illustrated in Figures 7 and 8. Figure 12 demonstrates the members after implantation. Figure 13 demonstrates the final position of the members after manipulation via probe 280, as shown in Figure 8.

However, Foley provides an image based procedure. Ellis teaches that current methods for computer-assisted interventions are based on one of four paradigms. Three out of four of these paradigms are image-based procedures. The remaining one paradigm is an imageless procedure in which tools and tracking devices are attached to a patient in order to guide the intervention free of imaging. See paragraphs 3-5. It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform an imageless procedure, as taught by Ellis, as a well-known alternative to an image-based procedure because the latter may be costly and logistically inconvenient (paragraph 16 of Ellis).

Claims 20-21, 31-32, 45-46, 75-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley et al. in view of Ellis as applied to claims 1, 22, 33 and 67 above, and further in view of Acker et al. (US Patent No. 6,332,089). Foley in view of Ellis is described above in the rejection of claims 1, 22, 33 and 67. However, the specifics of the imageless display are not provided in these

references. Acker discloses a method of performing medical procedures using two or more probes in an imageless environment. The procedure is performed using determined relative dispositions between the probes (*see* column 5, line 55 through column 6, line 8). The display for the invention need not show any image of the patient's tissue (column 12, lines 53-58). Plural probes can be coordinated with one another using information concerning their relative dispositions even without bringing the probes into close proximity to one another (*see* column 16, lines 46-65). *See* column 20, lines 9-64 for a written description of the display represented in Figure 18. Here there is shown icons relating to separate probe and a coordinate system, or atlas map, imposed behind the icons. If previously acquired image data is readily available and can be registered with the probe position data, the previously acquired image data can be displayed in registration with the indicia (*see* column 12, lines 54-58). Furthermore, column 2, line 57 through column 3, line 14 describes a probe function that can be implemented in an embodiment of Acker's system. The function provides for a probe to map the inner boundaries of the heart, thereby providing contour of a soft tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a method of display and operation of an imageless system, as taught by Acker and illustrated in Figure 18, in order to provide an operator with easy maneuverability and understanding in such an environment.

Regarding claims 82, 85, 88, and 92, Foley teaches a head-positioning probe specially designed to mate with the head of screws and can rotate them to receive rods, wires, plates, or other connecting implants. At least once these implants are received, the screw is locked in selected position and orientation.

Claims 81, 84, 87, 90 and 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley in view of Ellis as applied to claims 1, 22, 33, 53 and 67 above, and further in view of Rasche et al. (US Patent Pub. No. 2001/0034480) – herein referred to as Rasche. Foley in combination with Ellis is described above for the various interpretation for claims 1, 22, 33, 53 and 67. However, while Foley describes that the position and orientation of the screw heads is important in the procedure and that both the position and orientation are determined, Foley does not explicitly state that the determination is made with regard to six degrees of freedom. Rasche teaches systems and methods enabling the localization of objects. Rasche states, "In image-guided orthopedic surgery the positioning and orientation of, for example, screws in the bone tissue must be monitored with a high degree of accuracy. For <u>any type of minimum invasive intervention</u> the surgeon must be capable of accurately determining the spatial position of the relevant instruments relative to the patient (paragraph 2 – emphasis added)." Also, "The simulation of the projections is performed on the basis of the six object degrees of freedom (position and orientation) (paragraph 12)." Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to determine six degrees of freedom because, for any type of minimum invasive

intervention the surgeon must be capable of accurately determining the location of the instruments. Furthermore, Rasche teaches that position and orientation generally relates to six degrees of freedom, regardless of what the procedure is.

Claims 82-83, 85-86, 88-89 and 92-93 rejected under 35 U.S.C. 103(a) as being unpatentable over Foley in view of Ellis, and further in view of Shluzas (US Patent No. 6,648,888). The Examiner believes that Foley in combination with Ellis teaches the subject matter of claims 82, 85, 88 and 92 (as described above in the rejections of these claims). However, Shluzas more specifically teaches this subject matter, as well as the subject matter of claims 83, 86, 89 and 93. Foley and Ellis explicitly teach a screw positioning device comprising a localization marker. However, neither reference teaches a depressible member coupled to a mechanism for selectively engaging and disengaging a screw. Shluzas teaches a surgical instrument comprising a first device including an actuatable clamp for clamping on a fastener fixed to a first bone portion. Figure 19 illustrates the first device having a depressible handle portion **200** which closes a clamping portion as illustrated in Figures 14 and 15. This would obviously lock said first member in a selected position and selected orientation, at least with respect to the positioning device **10** of Figure 19. It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize an alternately designed head positioning probe, such as that taught by Shluzas in the system and methods of Foley in combination with Ellis in order to engage the screw and hold it in place while the top

portion (**438** of Figure 20) is locked in to the screw, which increase safety measures since this portion is generally below the skin when the rod (**380** of Figure 20) is inserted.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES KISH whose telephone number is (571)272-5554. The examiner can normally be reached on 8:30 - 5:00 ~ Mon. - Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art Unit 3737

JMK